SLUG: HEALTH/COVID/ANTIBODY TEST

Antibody Testing Provides Key Insights In Fight Against COVID-19

July 23, 2020. The human immune system has been optimized through evolution to neutralize pathogens that threaten human health. No academic laboratory or drug company has that capability. Antibodies, which are molecules that can bind to and neutralize a recognized threat, are key weapons in the immune system's disease-fighting arsenal.

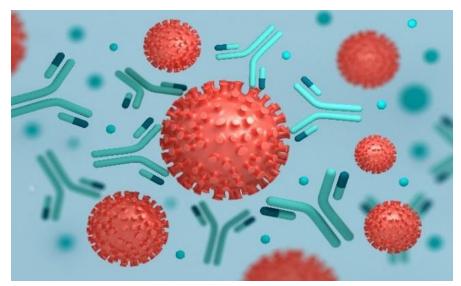
The antibodies produced by individuals infected with SARS-COV-2, the virus that causes COVID-19, offer important insights into key characteristics of the disease. Recognizing that value, public and private investment led to the rapid development of a variety of tests that can detect these antibodies in a blood sample. To date, the use of these tests, called serology tests, has been largely limited to identifying individuals who have been exposed to the virus.

Over 300 leading scientists in the U.S. have <u>called</u> for an expansion of serology testing to gather more of the important information that SARS-COV-2 antibodies can provide, which can aid in decisions ranging from how individuals may be treated to how society's re-opening can be enabled. Investment bank Jefferies agrees, as reflected in its recent <u>estimate</u> that testing should increase 10-fold from current levels.

However, the federal government, states and private industry are engaged in a <u>debate</u> as to how that additional testing should be funded. Pressure from the general public, armed with an understanding of the value of testing, offers a potential mechanism for resolving this debate.

What is a serology test and why is the resulting data important?

Each serology <u>test</u> evaluates a blood sample for the presence of antibodies that bind to a SARS-COV-2 antigen, a part of the SARS-COV-2 virus that is unique to that virus. Given this specificity, the accuracy for a positive result is over 99%, even in asymptomatic individuals. According to a recent <u>article</u> in the Journal of the American Medical Association (JAMA), the ability to accurately identify infected individuals regardless of symptoms is needed for virus tracing.



3D imaging of blood-based human antibodies (green) binding to a SARS-COV-2 like pathogen (red). This binding can be detected by standard serology tests. [Source – Shutterstock]

Serology testing can also <u>help identify antibodies in blood that can neutralize the SARS-COV-2 virus</u>. The findings of a workshop of over 300 experts, <u>reported</u> in July, concluded that this data is needed to help determine an individual's immune status, and more broadly, when herd immunity is reached in a population, key factors to managing COVID-19. The workshop was convened by the U.S. National Institutes of Health in May of this year.

<u>Neutralizing antibody</u> data from serology testing also helps identify recovered patients who are candidates to donate their blood as a <u>potential treatment for existing patients with severe disease</u>.



A blood tube from a recovered Covid-19 patient containing antibodies to SARs-COV-2, which could potentially be used to treat existing patients with severe disease. (Source – Shutterstock)

The ability to study the structure and activity of neutralizing antibodies identified by serology testing is invaluable to drug developers, who can engineer drug candidates in the laboratory to mimic those properties.

Finally, the potential value of a vaccine is measured in part by its ability to generate neutralizing antibodies to SARS-COV-2, a factor measured by serology testing. Vaccine trials can also be accelerated by using serology testing to identify communities with a high rate of infection. According to Dr. Cristina Cassetti, a deputy director at the NIH, these communities offer a rich pool of potential trial participants.

What don't serology tests tell us?

Serology tests do not provide information as to whether an individual has active disease.

Second, there is a possibility of a <u>false-negative result on a serology test</u>. This is particularly the case right after infection, where antibody responses are undetectable in many patients.

Finally, the <u>immune system has weapons other than antibodies</u>, including pathogen fighting T cells and natural killer cells. As such, a negative result from a serology test does not rule out the possibility that an individual is immune to the virus.

What is the major weakness with serology testing done to date?

According to Dr. Cassetti and her colleagues, the major existing gap with respect to serology testing is a need for more data, from a greater number of infected individuals, correlated with disease status, and measured over time. The government also needs to establish a system that allows for that data, which emanates from disparate testing sites, to be homogenized and properly evaluated by a single entity, the NIH, said Dr. Cassetti.

Only when these needs are met will experts be able to provide the type of reliable information that decision makers in hospitals, government, and in private industry need to play their respective roles in navigating society's path out of the COVID-19 pandemic.

Can this gap be overcome?

The major remaining barrier to realizing the potential benefits of serology testing is the ongoing debate about funding. A break in that debate may have surfaced today, as media outlets reported that the White House has agreed to \$16 billion in new funding for testing. However that amount, which represents approximately 20% of what Jeffries estimated was needed for more testing this season alone, is unlikely to end the debate altogether.

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